

PACKAGE LEAFLET

Omeprazole 20mg Capsules

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT OMEPRAZOLE 20 MG CAPSULES ARE AND WHAT THEY ARE USED FOR

The active ingredient, omeprazole, belongs to a group of medicines called "proton pump inhibitors". It works by reducing the production of acid in your stomach.

Omeprazole is used to treat the following conditions:

- *Reflux oesophagitis and Oesophageal reflux disease*, where acid from the stomach escapes into the food pipe causing pain, inflammation and heartburn.
 - Acid indigestion (*dyspepsia*) which can cause stomach pain and/or discomfort.
 - Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- For patients who have had previous trouble with an ulcer and need to continue therapy with a non-steroidal anti-inflammatory drug (NSAID), omeprazole can heal ulcers or prevent an ulcer developing. In such patients, omeprazole protects the stomach or duodenum whilst they are taking NSAIDs.
- Ulcers which are infected with bacteria called *Helicobacter pylori*.
 - Prevention of damage to the lungs caused by breathing in stomach fluids (acid aspiration), e.g. before an operation.
 - *Zollinger-Ellison syndrome*, when excess stomach acids are produced due to a growth in the pancreas.

2. BEFORE YOU TAKE OMEPRAZOLE 20 MG CAPSULES

If any of the following applies to you, speak to your doctor or pharmacist before you start taking Omeprazole Capsules as they may not be suitable for you.

Do not take Omeprazole 20 mg Capsules:

- If you are allergic (hypersensitive) to Omeprazole or any of the other
- ingredients of Omeprazole 20 mg Capsules.
- If you have a gastric ulcer and the possibility of malignancy has not been ruled out.

Take special care with Omeprazole 20 mg Capsules: It is important to talk to your doctor if you have any of the following conditions:

- If you have any liver problems
- If you have an intolerance to some sugars
- If your body does not absorb vitamin B₁₂ (cobalamin) very well

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

- Diazepam (for your nerves). Elimination of diazepam may be reduced during treatment with omeprazole.
- Phenytoin (for epilepsy). Elimination of

phenytoin may be reduced during treatment with omeprazole.

- Warfarin (for thinning of the blood). Elimination of warfarin may be reduced during treatment with omeprazole.
- Digoxin (for the heart). The bioavailability of digoxin can increase during treatment with omeprazole.
- Ketoconazole or itraconazole (for fungal infections). Absorption of ketoconazole or itraconazole may be reduced during treatment with omeprazole.

Pregnancy and breast-feeding:

Omeprazole 20 mg Capsules can be used during pregnancy and if you are breast-feeding.

Driving and using machines:

Your medicine does not usually affect your ability to drive or operate machinery.

Other precautions you should take:

If you are going to have an operation and anaesthetic (including at the dentist) tell your doctor or dentist that you are taking Omeprazole 20 mg Capsules.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE OMEPRAZOLE 20 MG CAPSULES

Your doctor has decided on the dose which is suited to you. The length of your course of treatment will depend on what condition you are suffering from. Always take Omeprazole 20 mg Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You can take your capsules with food or on an empty stomach at any time of the day. The capsules should not be chewed or crushed. They should be swallowed whole with a drink of water. If you have trouble swallowing the capsules, open the capsule and mix the granules with some fruit juice or yoghurt and then drink immediately.

Treatment for heartburn (Reflux oesophagitis and oesophageal reflux disease)

The usual dose for adults is 20 mg omeprazole taken once a day for 4 weeks. Your doctor may ask you to continue taking the capsules or increase the dose depending on how you respond to treatment. To stop your symptoms returning your doctor may tell you to continue to take 20 mg Omeprazole or reduce the dose to 10mg. For children the usual starting dose will be dependent on their weight and treatment should be given for a period of 4 - 12 weeks.

Relief of Acid Indigestion (Dyspepsia)

The usual dose is 10 mg or 20 mg once a day for a period of 2 - 4 weeks. Your doctor will tell you how long to take your capsules for. If you do not experience any improvement in your symptoms you should return to your doctor.

Treatment of ulcers in the upper part of the intestine (duodenal ulcer) and stomach (gastric ulcer)

The usual dose is 20 mg omeprazole once a day for a period of 4 - 8 weeks depending on your symptoms. Your doctor may increase the dose depending on how you respond to treatment. To stop your ulcer coming back, the usual dose is omeprazole 10 mg once daily unless your symptoms return. If your symptoms return, your doctor may increase the dose.

Treatment and prevention of stomach ulcers, duodenal ulcers and associated symptoms caused by NSAIDs

If you have previously had trouble with an ulcer and need to continue taking a NSAID the recommended dose is omeprazole 20 mg once daily. Your doctor will advise how long you need to take the capsules for.

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Treatment of Ulcers caused by infection with the bacteria called Helicobacter Pylori
The usual dose is omeprazole 40 mg once a day or 20 mg taken twice a day for a period of 1 - 2 weeks. Your doctor will also tell you to take one or two of the following antibiotics; amoxicillin, clarithromycin, metronidazole or tinidazole. Follow the directions for taking your medicine very carefully and if you are unsure about anything, ask your doctor or pharmacist.

Before a hospital operation when you are to be given a general anaesthetic
The usual dose is omeprazole 40 mg taken the evening before surgery, and another 40 mg dose two to six hours before surgery.

Zollinger - Ellison Syndrome
The usual starting dose is omeprazole 60 mg once a day. If the dose is more than 80 mg a day, half the dose should be taken in the morning and half at night. Your doctor will tell you how many capsules to take and when to take them.

If you take more Omeprazole 20 mg Capsules than you should:
If you (or someone else) accidentally take too many Omeprazole 20 mg Capsules, contact your doctor or pharmacist immediately.

If you forget to take Omeprazole 20 mg Capsules:
If you forget to take a dose, take it as soon as you remember. If it is nearly time for your next dose just take the next dose and forget about the one you missed. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Omeprazole 20 mg Capsules:
Always contact your doctor or pharmacist before you stop taking Omeprazole 20 mg Capsules. Stopping the treatment early can cause the problem to come back.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Omeprazole 20 mg Capsules can cause side effects, although not everybody gets them. These are usually mild and go away when you stop taking this medicine.

If the following happens, stop taking the capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction (angioedema): swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Side effects sometimes seen are:
Common more than one in a hundred people but less than one in ten:

- headache, diarrhoea, constipation, abdominal pain, nausea, vomiting and flatulence.

Uncommon more than one in a thousand people but less than one in a hundred:

- Dizziness, burning, prickling, tickling, tingling, light headedness, feeling faint, insomnia, vertigo, sleepiness, increased liver enzymes, rash, itching and general discomfort.

Rare more than one in ten thousand people but less than one in a thousand:

- mental confusion, agitation, aggression, depression, hallucinations, larger breasts, dry mouth, sensitivity to light, sore joints and muscles, increased sweating, swollen limbs, blurred vision, taste disorders, low blood sodium, swelling and soreness of the mouth and throat, wheezing, hair loss, impotence, slight increase in the risk of gut infection, kidney or liver problems, reduced blood cells, severe skin reactions.

Taking a proton pump inhibitor like omeprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your

doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Frequency not known
If you are on omeprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via The Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine

5. HOW TO STORE OMEPRAZOLE 20 MG CAPSULES

Keep out of the reach and sight of children.
This medicinal product does not require any special storage conditions.

Do not use Omeprazole 20 mg Capsules after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What Omeprazole 20 mg Capsules contains

- The active substance is omeprazole and each capsule contains 20 mg of omeprazole as gastro resistant granules.
- The other ingredients are sugar spheres, sodium starch glycolate, sodium laurilsulfate, povidone, potassium oleate, oleic acid, hypromellose, methacrylic acid - ethyl acrylate copolymer (1:1), triethyl citrate, titanium dioxide and talc. The capsule coating also contains gelatin, titanium dioxide (E171), quinoline yellow (E104), indigo carmine (E132) and erythrosine (E127). The printing ink contains shellac, polyvinylpyrrolidone, propylene glycol, sodium hydroxide and titanium dioxide (E171).

What Omeprazole 20 mg Capsules look like and contents of the pack

Each capsule has an orange body and blue cap and is marked with O20. The capsule contains white to beige gastro-resistant granules.

Omeprazole 20 mg Capsules are available in bottles of 28 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Somex Pharma,
600 High Road, Seven Kings
Ilford, Essex IG3 8BS

Manufacturer:
Teva Pharma, S.L.U. C/ C, nº 4,
Polígono Industrial Malpica,
Zaragoza, 50016, Zaragoza

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